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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/601,267    08/25/00    KEITH

W    9013-18

020792    HM12/1105  
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PO BOX 37428  
RALEIGH NC 27627

EXAMINER
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WILDER, C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED:

11/05/01

*9*

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/601,267

Applicant(s)  
WILLIAMS

Examiner  
CB Wilder

Art Unit  
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 29, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-27 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 17, 18, 26, 27, drawn to isolated promoter sequence, construct, vector and host cells.

Group II, claim(s) 11-13, drawn to a method of culturing cells.

Group III, claim(s) 14-16, drawn to method of screening of substance that modulate TR promoter activity .

Group IV, claim(s) 19-23, drawn to delivery system for neoplasia control.

Group V, claim(s) 24-25, drawn to method of treating neoplasia..

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: This application lacks a single inventive concept under PCT Rule 13.1 because the "special technical feature" is not new and does not provide a contribution over the prior art. Specifically an isolated promoter sequence derived from the

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telomerase RNA gene promoter having approximately 505 bp upstream of the transcription start site or a fragment thereof, capable of initiating transcription of DNA operably linked downstream of said promoter is known in the prior art. For example, Hickley et al. (Nucleic acids research, Vol. 26, No. 2, pages 532-536, January 15, 1998) teach and isolated promoter sequence derived from the telomerase RNA gene promoter and fragment thereof capable of initiating transcription of a DNA operably linked downstream of said promoter (see section entitled "DNA-sequence analysis of human and mouse telomerase RNA promoter regions" and Figure 3). The "special technical feature" does not define the claimed invention over the prior art as previously stated.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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#### *Sequence Listing*

4. Applicant's sequence amendment filed May 29, 2001 in Paper No. 8 is acknowledged and has been entered into the database. However, the claims are drawn to sequences depicted as Fig. 4a that are not represented by a sequence identifier (SEQ ID NO:). The specification and drawings also

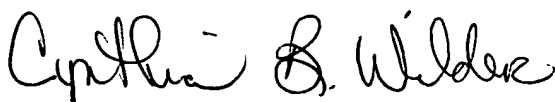
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contain sequences that are not represented by a sequence identifier. Applicant is required to amend the disclosure such that every unbranched sequence of ten or more nucleotides or unbranched sequence of four or more amino acids is represented by a sequence identifier (see MPEP 2422.03).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:30 am to 5:30 pm.

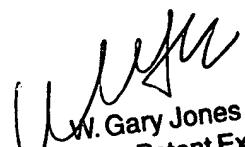
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.



Cynthia B. Wilder, Ph.D.

October 30, 2001



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600